

In re application of:

LEE et al.

Appl. No.: 10/535,624

Int'l. Filing Date: November 22, 2002

For: Antimicrobial Peptide Isolated from Halocynthia Aurantium

Confirmation No.: 1731

Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket: 2393.0010000/JUK/WBC

Information Disclosure Statement Under 37 C.F.R. § 1.97(b)

Mail Stop PCT

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying IDS Forms are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of documents FP1 and NPL1-NPL24 are submitted.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached IDS Forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed IDS Forms, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

William B. Coblentz Agent for Applicants

Registration No. 57,104

Date:

1100 New York Avenue, N.W. Washington, D.C. 20005-3934

(202) 371-2600

Equivalent of Form PTO/SB/08A (07-05) Approved for use through 07/31/2006.

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

		Under t	Peacrwork Reduction Act of 199	no persons are required to respond to a collect	oformation unless it contains a valid OMB control number
Substitute	for form	1449/		Complete	nown
				Application Number	10/535,624
INFOR	RMA'	TION	DISCLOSURE	Int'l. Filing Date	November 22, 2002
			APPLICANT	First Named Inventor	In-Hee LEE
			eets as necessary)	Art Unit	To Be Assigned
			•	Examiner Name	To Be Assigned
Sheet	1	of	1	Attorney Docket Number	2393.0010000/JUK/WBC

			U.S. PATENT DOC	CUMENTS	
Examiner Cite Initials No.1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
	Number-Kind Code ^{2 (If Known)}	MIWI-DD-1111	Applicant of Cited Document	or Relevant Figures Appea	
					
					†
			 		
			 		

		FC	REIGN PATENT DO	DCUMENTS		
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
	FP1	WO 98/20028 A2	05/14/1998	The Regents of the University of California		
	*					

Examiner	Date	
Signature	Considered	
	<u></u>	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 'Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if

document by the appropriate symbols as indicated on the document under wire distinctions. Opposition to push the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

Substitute for f	form 1449/PT	0		Co	mplete if Known
				Application Number	10/535,624
INFORM	IATION	DIS	CLOSURE	Int'l. Filing Date	November 22, 2002
STATEM	STATEMENT BY APPLICANT (Use as many sheets as necessary)			First Named Inventor	In-Hee LEE
				Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	1	of	3	Attorney Docket Number	2393.0010000/JUK/WBC

		1	
		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume issue number(s), publisher, city and/or country where published	T ²
	NPL1	Azumi, K., et al., "Halocyamines: Novel Antimicrobial Tetrapeptide-like Substances Isolated from the Hemocytes of the Solitary Ascidian Halocynthia roretzi," Biochem. 29:159-165, American Chemical Society (1990)	
	NPL2	Azumi, K., et al., "Inhibitory Effect of Halocyamine, an Antimicrobial Substance from Ascidian Hemocytes, on the Growth of Fish Viruses and Marine Bacteria," Experientia. 46:1066-1068, Birkhäuser Verlag (1990)	
	NPL3	Bellm, L., et al., "Protegrins: New Antibiotics of Mammalian Origin," Expert Opin. Investig. Drugs. 9:1731-1742, Ashley Publications Ltd. (2000)	
	NPL4	Falla, T., et al., "Mode of Action of the Antimicrobial Peptide Indolicidin," J. Biol. Chem. 271:19298-19303, The American Society for Biochemistry and Molecular Biology, Inc. (1996)	
·	NPL5	Fehlbaum, P. et al., "Structure-Activity Analysis of Thanatin, a 21-Residue Inducible Insect Defense Peptide with Sequence Homology to Frog Skin Antimicrobial Peptides," Proc. Natl. Acad. Sci. USA. 93:1221-1225, National Academy of Sciences (1996)	
	NPL6	Goraya, J., et al., "Peptides with Antimicrobial Activity from Four Different Families Isolated from the Skins of the North American Frogs Rana Luteiventris, Rana Berlandieri and Rana Pipiens," Eur. J. Biochem. 267:894-900, Federation of European Biochemical Societies (2000)	
	NPL7	Hancock, R.E., et al., "Cationic Bactericidal Peptides," Adv. Microbial Physiol. 37:135-175, Academic Press Inc. (1995)	
	NPL8	Hancock, R.E., et al., "The Role of Antimicrobial Peptides in Animal Defenses," Proc. Natl. Acad. Sci. USA. 97:8856-8861, National Academy of Sciences (2000)	
	NPL9	Hetru, C., et al., "Androctonin, A Hydrophilic Disulphide-Bridged Non-Haemolytic Anti-Microbial Peptide: A Plausible Mode of Action," <i>Biochem. J.</i> 345:653-664, Portland Press Ltd. (2000)	
	NPL10	Iwanaga, S., et al., "New Types of Clotting Factors and Defense Molecules Found in Horseshoe Crab Hemolymph: Their Structures and Functions," J. Biochem. 123:1-15, The Japanese Biochemical Society (1998)	
Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute for form	1449/PTC			Со	mplete if Known
				Application Number	10/535,624
INFORMAT	TION I	DISC	CLOSURE	Int'l. Filing Date	November 22, 2002
STATEMEN	STATEMENT BY APPLICANT			First Named Inventor	In-Hee LEE
			s necessary)	Art Unit	To Be Assigned
				Examiner Name	To Be Assigned
Sheet	2	of	3	Attorney Docket Number	2393.0010000/JUK/WBC

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL11	Jang, W. S., et al., "Halocidin: A New Antimicrobial Peptide from Hemocytes of the Solitary Tunicate, Halocynthia Aurantium," FEBS Lett. 521:81-86, Elsevier Science B.V. (May 2002)	
	NPL12	Krause, A., et al., "LEAP-1, A Novel Highly Disulfide-Bonded Human Peptide, Exhibits Antimicrobial Activity," FEBS Lett. 480:147-150, Elsevier Science B.V. (2000)	
	NPL13	Lee, I. H., et al., "Styelins, Broad-Spectrum Antimicrobial Peptides from the Solitary Tunicate, Styela clava," Comp. Biochem. Physiol. B Biochem. Mol. Biol. 118B:515-521, Elsevier Science Inc. (1997)	
	NPL14	Lee, I. H., et al., "Clavanins, ά-helical Antimicrobial Peptides from Tunicate Hemocytes," FEBS Lett. 400:158-162, Elsevier Science B.V. (1997)	:
	NPL15	Lee, I. H., et al., "Effects of pH and Salinity on the Antimicrobial Properties of Clavanins," Infection and Immunity. 65:2898-2903, American Society for Microbiology (1997)	
	NPL16	Lee, I. H., et al., "Dicynthaurin: An Antimicrobial Peptide from Hemocytes of the Solitary Tunicate, <i>Halocynthia aurantium</i> ," <i>Biochim. Biophys. Acta.</i> 1527:141-148, Elsevier Science B.V. (May 2001)	
	NPL17	Lehrer, R. I., et al., "DEFENSINS: Antimicrobial and Cytotoxic Peptides of Mammalian Cells," Annu. Rev. Immunol. 11:105-128, Annual Reviews Inc. (1993)	
	NPL18	O'Neil, D. A., et al., "Expression and Regulation of the Human β-Defensins hBD-1 and hBD-2 in Intestinal Epithelium," <i>J. Immunol.</i> 163:6718-6724, The American Association of Immunologists (1999)	
	NPL19	Piers, K. L., et al., "Improvement of Outer Membrane-Permeabilizing and Lipopolysaccharide-Binding Activities of an Antimicrobial Cationic Peptide by C-Terminal Modification," Antimicrob. Agents Chemother. 38:2311-2316, The American Society for Microbiology (1994)	
	NPL20	Romeo, D., et al., "Structure and Bactericidal Activity of an Antibiotic Dodecapeptide Purified from Bovine Neutrophils," J. Biol. Chem. 263:9573-9575, The American Society for Biochemistry and Molecular Biology (1988)	

Examiner	Date	
Signature	Considered	

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Application Number

d for use through 07/31/2006. OMB 0651-0031 Office; U.S. DEPARTMENT OF COMMERCE ation unless it contains a valid OMB control number.

10/535,624

2393.0010000/JUK/WBC

Complete if Known

Under the	e Paperwor
for form	1449/PTO

3

Substitute

Sheet

INFORM STATEM

of

1ATION DISCLOSURE	Int'l. Filing Date	November 22, 2002	
MENT BY APPLICANT	First Named Inventor	In-Hee LEE	
(Use as many sheets as necessary)	Art Unit	To Be Assigned	
	Examiner Name	To Be Assigned	

Attorney Docket Number

NON DATENT I TERRATURE DOCUMENTS

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher, city and/or country where published	T ²
	NPL21	Taylor, S. W., et al., "Styelin D, an Extensively Modified Antimicrobial Peptide from Ascidian Hemocytes," J. Biol. Chem. 275:38417-38426, The American Society for Biochemistry and Molecular Biology (2000)	
	NPL22	Zhang, L., et al., "Interaction of Cationic Antimicrobial Peptides with Model Membranes," J. Biol. Chem. 276:35714-35722, The American Society for Biochemistry and Molecular Biology, Inc. (July 2001)	
	NPL23	Zhao, C., et al., "cDNA Cloning of Clavanins: Antimicrobial Peptides of Tunicate Hemocytes," FEBS Lett. 410:490-492, Elsevier Science B.V. (1997)	
	NPL24	Zhao, C., et al., "cDNA Cloning of Three Cecropin-Like Antimicrobial Peptides (Styelins) from the Tunicate, Styela clava," FEBS Lett. 412:144-148, Elsevier Science B.V. (1997)	
			L

Examiner Date Signature Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional).

Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.